

REMARKS

A. Status of the Claims

Claim 1 has been amended to more clearly claim the Applicants' invention. Support for the amendment may be found in the Specification, at least, at page 6, lines 3-14. Claim 30 has been amended to correct a typographic error. No new matter is added by the amendments. Claims 1-32 are currently pending and presented for reconsideration.

B. Information disclosure Statement

The Official Action states that an English translation was not submitted for a reference provided with the Information Disclosure Statement filed November 30, 2006. Applicants note that a supplemental Information Disclosure Statement was filed December 18, 2006, including a copy of an English translation of this reference, C51 (Lu *et al.*, *Soybean Bulletin* 2001). Applicants respectfully request that the cited reference be considered. An additional Supplemental Information Disclosure Statement is also enclosed.

C. Claim Rejection Under 35 U.S.C. § 112, First Paragraph – Written Description

The Action maintains the rejection of claims 1-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, it is asserted that the specification fails to provide an adequate description of the genus of soybean plants that are agronomically elite and have a mean whole seed total protein content between 45-50%, a mean whole seed total protein plus oil content of between 64-70%, and a commercially significant yield, as well as parts thereof and methods of use, in terms of their genetic, morphological, and/or physiological characteristics.

Applicants initially note in response that claim 1 has been amended herein to recite soybean variety SN30003 as a parent plant. Each of claim 1-29 now incorporate this element by dependency on claim 1 or otherwise specify method steps involving use of variety SN30003 as a

parent plant. These claims specify soybean plants demonstrating (1) agronomically elite characteristics; (2) mean whole seed total protein content of between 45-50%; (3) mean whole seed total protein plus oil content of between 64-70%; (4) mean whole seed total oil content of at least 20%; (5) commercially significant yield; and (6) wherein the plants are progeny of SN30003 or of a subsequent generation of such a plant. This subject matter is fully described in the Specification in compliance with § 112, first paragraph. In particular, the Specification explicitly provides multiple examples demonstrating that the Applicants were in possession of this subject matter at the time of filing. This was also noted in the Response filed October 25, 2006.

For instance, in Example 1, soybean variety 0007583 is shown to have been derived from a cross with variety SN30003, and selected based on the criteria listed above, including seed yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity, plant height, and seed oil and protein content, among others (Specification, page 44, lines 5-7; page 45, lines 2-4; page 49, lines 18-20). Likewise, as shown in Example 5, soybean variety 0137441 is derived from a cross with variety SN30003, and selected based on agronomic characteristics including yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity, plant height, and seed oil and protein content (Specification, page 57, lines 6-19). Based on the working examples and knowledge of one of skill in the art of plant breeding, one of skill in the art could also generate new varieties using the same protocols described therein.

The Action asserts that “one skilled in the art cannot produce the same variety twice by using the exact same original parents and the same selection techniques” (Action, page 6, 1st paragraph). Applicants note in response that the claimed invention does not relate to “producing the same variety” again, but instead relates to producing additional soybean varieties, utilizing

the recited parent plant(s) and selection methods. Given the disclosure of the Specification, for instance that SN30003 is a particularly useful parent plant (which was not previously recognized in the art) in obtaining soybean plants that display the recited traits, one of skill in the art of plant breeding could clearly make appropriate crosses and select resulting progeny plants, without experimentation that is undue in the art of plant breeding. Additionally, the described varieties, for instance 0007583 or 0137441, or others descended from SN30003 could themselves be used as parents in following the described protocols, as is noted in the Specification at least at page 6, lines 3-14.

The Action also asserts that “a breeder...cannot predict the final resulting lines he develops, except possibly in a very gross and general fashion” [Action, page 5, top paragraph]. Applicants respectfully note that numerous characteristics of the claimed plants, and methods to produce them, are clearly defined in the specification and in the art, and the Action has not disputed this. Further, as noted in the previous response, the claims do not relate to undefined characteristics; nor do they require that every progeny plant of a cross between SN30003 and itself or another plant must display the recited characteristics. Instead, the specification clearly teaches one of skill in the art that, given the SN30003 starting material, one can utilize the teachings of the present specification as well as knowledge in the art, to derive the claimed plants by the disclosed breeding and selection processes in combination with the knowledge of one skilled in the art. Thus, Applicants respectfully request withdrawal of this rejection.

Applicants note that claims 30-32 have also been included in the above-mentioned rejection. However, that these claims are independent method claims. No aspect of the previous Actions indicate how this rejection should properly apply to these method claims. The rejection was apparently made based on the assertion that only certain soybean varieties were in the

possession of the inventors, which does not indicate that the method was not in the possession of the inventors. Indeed, as the Action acknowledges that such soybean varieties were in fact identified, Applicants understand that the methods used to obtain them, which are described in the Specification, must have been in the possession of the inventors. In fact the working examples fully support the claimed method.

The Action further does not dispute that the meaning of the claim terms, for instance regarding characteristics for selection. Likewise, variety SN30003 to be utilized in practicing the claimed invention is clearly described, and is noted to be available from the USDA germplasm collection (see previous response, and as acknowledged in the present Action). The present application teaches that SN30003 may be used as recited by claims 30-32, and clearly demonstrates that the inventors were in possession of the claimed invention. The Action has therefore not shown how the Written Description Requirement has not been met according to MPEP 2163.04, which states that

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is *presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption*. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

(emphasis added). Applicants therefore respectfully request withdrawal of the rejection.

D. Claim Rejection Under 35 U.S.C. § 112, First Paragraph- Enablement

The Action rejects claims 1-29 and 32 under 35 U.S.C. § 112 based on the assertion that the specification does not reasonably provide enablement for any and every agronomically elite

soybean plant having the claimed mean whole seed protein content and mean whole seed total protein plus oil content, and a commercially significant yield. The Action further states, in view of the considerations of *in re Wands*, that undue experimentation would be necessary to practice the invention.

In response, Applicants note initially that the claims have been amended herein to recite soybean plants derived from a cross with variety SN30003 displaying a mean whole seed total protein content between 45-50%, a mean whole seed total protein plus oil content of between 64-70%, a mean whole seed total oil content of at least 20%, and a commercially significant yield, as well as tissue cultures and methods for developing them. The Specification provides sufficient disclosure to satisfy the enablement requirement of 35 U.S.C. § 112, First Paragraph, for this subject matter, in that the Specification provides working examples within the scope of the claims, and the teachings of the Specification combined with the knowledge of one of ordinary skill in the art provides sufficient guidance to practice the invention without undue experimentation.

For instance, and as noted previously, in Examples 1 and 5, soybean varieties 0007583 and 0137441 are identified, derived from initial crosses of varieties A2553xSN30003, and AG3302xSN30003, respectively, and selected based on agronomically elite criteria including seed yield, lodging resistance, emergence, seedling vigor, disease tolerance, maturity plant height, and seed oil and protein content, among others (*e.g.* Specification, page 44, lines 5-7; page 49, lines 18-20; page 45, lines 2-4; also Specification, page 57, lines 17-19). Variety 0007583 is further described as possessing a protein content of 46.2% (Tables 2, 7), and an oil content of 20.4% (*e.g.* Table 2, Table 7, leading to an oil + protein content of 66.6%. Yield of 007583 is reported as 54.7 bu/ac in Table 7, and yield of 00137441 is reported as 45.2 bu/ac in

Table 24. Variety 0137441 is further described as possessing a protein content of 45.4% and an oil content of 20.4%, leading to an oil + protein content of 65.8% (Table 24 at page 59). Thus, at least these two examples demonstrate that use of SN30003 as a parent in a soybean breeding process can lead to identification of the claimed soybean varieties. Whether one skilled in the art could re-produce these varieties using the same parents and the same selection techniques is not relevant to the enablement of the claimed invention, since the claims relate not to producing identical varieties. Instead, the claims relate to producing additional varieties displaying the claimed characteristics.

Applicants have noted that each of these characteristics for progeny plants may be determined by one of skill in the art, and this assertion has not been challenged in the Action. Although the Action asserts that it would require undue trial and error experimentation for one skilled in the art to make and use the invention because one would have to screen thousands of soybean plants to determine which, if any, when crossed by a claimed parent would produce soybean plants in accordance with the claims, Applicants respectfully submit that screening of multiple plants, even thousands of plants, is routine in the art of plant breeding, and does not in any way represent undue experimentation, given that the claimed agronomic traits are clearly defined in the Specification, well known in the art, and multiple working examples of successful use of such a breeding scheme and selection method are provided. This is the epitome of routine experimentation.

The Action does not show how any of the recited crossing and selection steps are other than routine, once variety SN30003 has been identified and used as a parent for subsequent breeding work. The Specification contains extensive guidance on the breeding methods that are used (*e.g.* page 12, line 21, to page 25, line 5). The Specification also provides guidance as to

how such measurements may be made, for instance, by testing candidate soybean plants for yield, oil, and protein content, as well as for agronomic characteristics, all of which may be readily evaluated by one of skill in the art. Thus, just as one of skill in the art may screen a plant population grown from seeds identified, for instance, as being of variety 007583 to determine whether they meet the claimed agronomic criteria, one may use the same techniques to determine whether any other progeny (and/or subsequent descendants) of a cross with SN30003 may also meet the claimed criteria. Applicants further respectfully request that the nature of the alleged “undue experimentation” be defined, in that “[t]ime and difficulty of experimentation are not determinative [of undue experimentation] if they are merely routine” [MPEP, 2164.06; “Quantity of Experimentation”].

Thus, given the undue experimentation factors set out in MPEP 2164.01(a) (*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), Applicants respectfully submit that no undue experimentation would be required to practice the claimed invention. Applicants have clearly demonstrated possession of multiple soybean varieties displaying the claimed attributes, as well as successful use of variety SN30003 in plant breeding to obtain soybean varieties as claimed.

The Action also asserts that, regarding claims 10-14, “there is no guidance regarding any single locus conversion,” and that undue experimentation would be needed in that “thousands of plants would need to be screened” to determine which might display the claimed characteristics (Action, page 6, bottom). Applicants traverse as follows.

Applicants note that the term “single locus conversion” is explicitly defined in the Specification, at page 41, lines 1-5. The provided definition is consistent with that found in the art. Methods of soybean backcross breeding are well known in the art, and are discussed, for

instance in the Specification at page 13, third paragraph and following, and page 26, line 1 and following. An example of a single locus conversion, relating to disease resistance but generally applicable, is provided at page 29. Applicants find no basis for the assertion that there is no guidance for any single locus conversion.

Regarding the assertion that thousands of plants would need to be screened, the Action provides no data or reference to demonstrate that is the case. Even if it were assumed to be the case, only for the purpose of this response, Applicants respectfully submit that such experimentation would not be considered undue in the art of plant breeding, as noted above. Applicants further do not understand the Action's description of a single locus conversion as being "insert[ed] into the genome of the claimed invention" [Action, page 6, bottom], especially as it would relate to any method claims. If the Action means to refer to a transgenic soybean plant comprising a certain transgenic insertion event, Applicants submit that identifying the presence of such a transgene in a candidate plant or population of plants by various molecular techniques such as PCR, Southern blotting, *etc.* is routine and widely practiced. Likewise, identifying whether the agronomic characteristics of a given plant or plant population fall within the claimed characteristics is also well within the skill of a typical plant breeder.

The Action also asserts, regarding claims 15-18 and 23-32, that without knowledge of the other soybean plant to be used in a cross with SN30003, it would require undue experimentation to produce the claimed soybean plants. Applicants note that while there is a level of unpredictability in the general plant breeding arts, choices of parental plants are well within the skill of a typical plant breeder, and guidance is provided for instance at page 13, 2nd paragraph. In particular, the specifically recited choice of SN30003 as (at least) one of the parent or ancestral plants, as is claimed, renders the breeding steps routine. Applicants acknowledge that

not every cross with SN30003 would be expected to result in a claimed plant, as noted in the specification. Nevertheless, given that SN30003 has been identified as an appropriate parent or ancestral plant to allow the practice of the claimed invention, the other parent plant(s) can routinely be selected according to the breeder's objectives.

In view of the foregoing, withdrawal of the rejection is respectfully requested.

E. Claim rejection under 35 U.S.C. § 102(b)

The Action rejects claims 1-14 and 16-29 under 35 U.S.C. § 102(b) as being anticipated by Cober *et al.* (*Crop Sci.* 40:39-42, 2000), in view of Poehlmann *et al.*, (*Breeding Field Crops* 4th ed., page 300-318). Applicants respectfully traverse.

The Action alleges that “soybean plants (*sic*) are typically made up of at least 20% oil” [Action, page 8], in view of Poehlmann *et al.* Applicants submit that such a statement is a gross over-simplification if not a misunderstanding of the field of soybean breeding. As noted in the Specification, for instance at page 3, soybean breeders have long noted that levels of protein, oil, and seed yield are negatively correlated in soybeans. That is, selecting for high protein results in decreased yield and oil content. Thus, a soybean variety displaying 20% oil in its seed would not typically possess high seed protein (particularly 45% protein) or yield.

The Cober (2000) reference demonstrates that the Action's characterization of Poehlmann *et al.* is not accurate. For instance the very first sentence in the abstract of the cited Cober reference notes this in regard to seed yield and seed protein. Likewise, Hartwig as cited in the Specification at page 3, line 8 (and see cited references C17 and C18), describes this in relation to seed oil and protein content. The Poehlmann reference, to the extent that it is true, is referring very generally to an average protein and oil content, without considering yield or other agronomic characteristics, and without specific regard to high protein (*e.g.* 45% protein) varieties. While soybean varieties with 40% protein in seeds may indeed simultaneously possess

20% oil content, the present claims recite that 45% protein is required along with 20% oil and significant yield. As protein content is selected to increase from 40% to 45%, one of skill in the art of soybean breeding at the filing date of the present application would understand that oil content (and yield) would inevitably decline.

Wehrmann *et al.* (1987) as discussed in the Specification at page 4, lines 7-14, further supports this, as the high protein line was found to possess lower yield and oil content. Thus, the Action apparently misunderstands Poehlmann when citing it to state that a soybean plant (*sic .i.e.* seed) is typically made up of at least 20% oil. This is simply not the case, especially if a high protein plant and its seed, such as comprising 45% seed protein, were being studied.

Further, although Cober notes in Table 1 that the variety “Maple Glen” showed 45.7% protein and 20.1% oil, from 2 trials grown at a single location in 1996, Table 3, with additional “Maple Glen” data, shows only 42.7% protein from 6 locations in the following year. The present specification explicitly defines “commercially significant yield” as being defined over at least 15 environments (Specification, page 38), and the described soybean varieties were all tested for their characteristics over multiple locations and years (*e.g.* see page 44 regarding testing of 007583). Thus, “Maple Glen,” or the other varieties of Cober, although characterized in the Action as inherently having at least 20% oil, would not be understood by one of skill in the art to represent a variety displaying the claimed characteristics, in terms of each of its protein and oil contents, and yield, as defined by and understood in light of the Specification, and in particular in terms of simultaneously displaying 45-50% seed protein, 20% seed oil, protein plus oil of at between 64-70%, and commercially significant yield. The plants of Cober are thus clearly distinguishable from the claimed soybean plants. Withdrawal of the rejection is respectfully requested.

The Action also rejects claims 1-14 and 16-29 under 35 U.S.C. § 102(b) as being anticipated by Wilcox (1998), citing Poehlmann *et al.* as showing that soybean varieties typically display at least 20% oil content (in their seeds). As noted above, Poehlmann is apparently misunderstood, at least with regard to soybean plants displaying 45% seed oil content. One of skill in the art would not expect that such a plant would also inherently or typically simultaneously comprise 20% oil. Thus, the Poehlmann reference is not properly used to demonstrate that the plants of Wilcox would inherently have 20% oil content. The plants of Wilcox are therefore distinguishable from the claimed soybean plants. Withdrawal of the rejection is thus respectfully requested.

F. Claim rejection under 35 U.S.C. § 102(b) or alternatively 35 U.S.C. § 103(a)

The Action maintains the rejection of claims 15-32 under 35 U.S.C. § 102(b) or alternatively under 35 U.S.C. § 103(a) as obvious over Wilcox *et al.* (*Crop Sci.* 35:1036-1041, 1995). Applicants respectfully traverse.

Regarding claim 15, Applicants respectfully submit that strains CX1038-14 and CX-1307-205 are non-elite, and do not display 20% seed oil content, while neither Cutler 71 nor Hamilton display total protein content of 45%, nor protein plus oil content of between 64-70%. Again, the data that is provided by Wilcox in Table 1 instead indicate that simultaneous maintenance of yield, protein, and oil content of each of the parental lines was *not* achieved in the reported progeny lines. For instance, the lines displaying at least 45% protein each had less than 20% oil, while the lines displaying at least 20% oil each had less than 45% seed protein. In view of this and the amendments to the claims, Applicants respectfully submit that the rejection is mistaken, and request that it be withdrawn.

Regarding claims 16-32, although the reference states that “high seed protein can be backcrossed...suggesting the absence of physiological barriers to combining high seed protein

with high yield”, as noted by the Action, the reference does not however state the same with respect to selection for 20% oil content in the context of the claimed seed yield and protein content, or demonstrate success of such an undertaking. Again, the “trend” noted for increased oil content in backcross generations appears incorrect, in that the BC1 and BC3 lines do not significantly differ with respect to their oil content

A soybean breeder would not have any reasonable expectation of success in achieving creation of the presently claimed soybean varieties upon reading the Wilcox reference, since the data provided by Wilcox indicate, again, that simultaneous maintenance of protein, oil, and yield at the claimed levels in progeny lines was not achievable. Again as noted above, the Poehlmann reference is not properly applied to show that soybeans inherently possess 20% (seed) oil. The Wilcox reference in fact teaches away from any expectation of such breeding success, notwithstanding the assertions of the present and previous Actions. Applicants therefore respectfully request withdrawal of the rejection.

G. Claim rejection under 35 U.S.C. § 103(a)

Claims 15 and 30-32 are again rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilcox (1998). In this rejection, Conway (U.S. Patent 6,140,556) is not recited, but is assumed to still be relevant. Applicants respectfully traverse.

Applicants initially disagree with the assertion that Wilcox “teaches an agronomically elite soybean plant, namely C1944...” This line is a breeding line, specifically described as being useful for further breeding, and is not itself an elite line or variety. Applicants further note that neither C1944 nor C1945 of Wilcox display at least 20% seed oil content. In fact, consistent with all of the other references cited in this Action, Wilcox (1998) describes no soybean varieties that display, simultaneously, the claimed levels of protein, oil, and yield. In total, this Wilcox

reference, as well as the other cited references including Poehlmann, the Specification, and the knowledge of one of skill in the art of soybean breeding, make it clear that obtaining a soybean variety that simultaneously displays the claimed protein, oil, and yield was not achieved in the art prior to the filing date of the present application. And, taken as a whole, these references clearly teach away from any expectation that the presently claimed varieties could be bred. In view of this, removal of the rejection is respectfully requested.

H. Conclusion

In view of the above, it is submitted that the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned attorney at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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